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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,844	03/04/2004	Peter G. Zaphiropoulos	2921-0145P	5375

2292 7590 01/23/2006

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,844	ZAPHIROPOULOS ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Zaphiropoulos et al.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 13, drawn in part to an isolated human protein, which is essentially comprised of SEQ ID NO. 1, a medicament comprising a protein according to any of claims 1-4, classified in class 530, subclass 350.

II. Claims 5 and 15-17, drawn in part to a medicament, a probe, a primer, and a diagnostic reagent comprising a nucleic acid encoding a protein according to any of claims 1-4, classified in class 536, subclass 23.1.

III. Claim 6, drawn in part to a method of treating a condition involving tumors comprising administering a protein according to any of claims 1-4 to a patient in need thereof, classified in class 514, subclass 2.

IV. Claims 6 and 14, drawn in part to a method of treating a condition involving tumors comprising administering a nucleic acid encoding a protein according to any of claims 1-4 to a patient in need thereof, classified in class 514, subclass 44.

V. Claim 7, drawn in part to a method of in vitro or in vivo diagnosis, wherein a protein according to any of claims 1-4 is used, classified in class 435, subclass 7.1.

VI. Claim 7, drawn in part to a method of in vitro or in vivo diagnosis, wherein a nucleic acid encoding a protein according to any of claims 1-4 is used, classified in class 435, subclass 6.

VII. Claim 8, drawn to a method of screening wherein a library of suitable candidate compounds is screened for modified drugs using a protein according to any of claims 1-4, as a lead compound, classified in class 435, subclass 4.

VIII. Claim 9, drawn to a method of synthesis of a modified drug, wherein a protein according to any of claims 1-4 is used, classified in class 435, subclass 183.1, for example.

IX. Claims 10 and 14, drawn to a modified drug identified by the method according to claim 8, or synthesized by the method according to claim 9, classified in class 530, subclass 300, for example.

X. Claims 11 and 13, drawn in part to an antibody which specifically binds to a protein according to any of claims 1-4, a kit comprising said antibody, classified in class 530, subclass 387.1.

XI. Claim 12, drawn to a recombinant cell expressing an antibody, classified in class 435, subclass 252.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are

structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While a polypeptide of group I can be made using the polynucleotides of group II, the polypeptide can also be made by another and materially different process, such as by peptide synthesis or purification from the natural source. Further, the polynucleotide may be used for the processes other than the production of the protein, such as nucleic acid hybridization. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. Furthermore, a search of the nucleic acid molecules of group II would also requires an oligonucleotide search, which is not likely to result in relevant art with

respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of groups I and II together.

Group I and any one of groups III, V, VII, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to generate antibodies as opposed to being used for treating a condition, in vitro or in vivo diagnosis, screening a compound or syntheses of a modified drug.

Searching the inventions of group I and groups III, V, VII and VIII together would impose serious search burden. The inventions of group I and groups III, V, VII and VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the methods of inhibiting, diagnosing, screening or synthesizing are not coextensive. Groups III, V, VII and VIII encompass molecules which are claimed in terms of candidate compounds or modified drugs, which are not required for the search of group I. Moreover, the search for groups III, V, VII and VIII would require a text search for the method steps. Prior art which teaches a polypeptide would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Group I and any one of groups IV and VI are unrelated because the product of group I is not used or otherwise involved in the process of groups IV and VI.

Group II and any one of groups III, V, VII and VIII are unrelated because the product of group II is not used or otherwise involved in the process of groups III, V, VII and VIII.

Group X and any one of groups III-VIII are unrelated because the product of group X is not used or otherwise involved in the process of groups III-VIII.

Group XI and any one of groups III-VIII are unrelated because the product of group XI is not used or otherwise involved in the process of groups III-VIII.

Groups I and X are distinct. While the inventions of both group I and group X are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group X encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group X are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group X is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Moreover, the polypeptide of group I can be used in another materially

different process as opposed to its use for production of the antibody of group X, such as in a pharmaceutical composition, or in assays for the identification of agonists or antagonists of the protein.

Groups I and XI, groups II and XI are distinct from each other because a recombinant cell of group XI does not express the protein of group I, and does not comprise the nucleic acid of group II. Claims II and X are unrelated because the nucleic acid of group II does not encode the antibody of group X.

Group II and any one of groups VI and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to make proteins as opposed to being used for treating a condition, in vitro or in vivo diagnosis.

Searching the inventions of group II and groups IV and VI together would impose serious search burden. The inventions of group II and groups IV-VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the nucleic acids and the methods of inhibiting, or diagnosing are not coextensive. Groups IV and VI encompass method steps such as administering to a patient a nucleic acid, which are not required for the search of group II. Moreover, the

search for groups IV and VI would require a text search for the methods. Prior art which teaches a nucleic acid would not necessarily be applicable to the method of using the nucleic acid. Moreover, even if the nucleic acid product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating a condition using a protein (group III), the method of treating a condition using a nucleic acid (group IV), a method of diagnosis using a protein (group V), a method of diagnosis using a nucleic acid (group VI), a method of screening a drug (group VII), and a method of synthesis of a drug (group VIII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. For group III, a protein is administered to a patient, for group IV, a nucleic acid is administered to a patient, for group V, a protein is used for diagnosis, for group VI, a nucleic acid is used for diagnosis, for group VII, a library of suitable candidate compounds is screened, and for group VIII, a drug is synthesized. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III-VIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups III-VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups III-VIII together.

The antibody of group X and recombinant of cell of group XI are structurally and functionally distinct. While the antibody of group X can be made using the recombinant cells of group XI, the antibody can also be made by another and materially different process, such as synthesis or purification from the natural source. Furthermore, searching groups X and XI together would impose a serious search burden. In the instant case, the search of the antibodies and the recombinant cells are not coextensive. The inventions of groups X and XI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups X and XI together.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit: 1643
Jan. 19, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER